K070005

510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

AUG 15 2007

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone No.: 781-861-4467
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Prepared:

June 28, 2007

Device Name:

HemosIL RecombiPlasTin 2G

Regulatory Information:

864.7750 81GJS	Prothrombin Time Test Test, Time, Prothrombin	Class II
864.7340 81GIS	Fibrinogen Determination System Test, Fibrinogen	Class II

Predicate Device:

K043184 HemosIL RecombiPlasTin

Device Description:

The RecombiPlasTin 2G reagent is formulated to be insensitive to therapeutic levels of heparin. In the PT test, the addition of the tissue thromboplastin (RecombiPlasTin 2G reagent) to the patient plasma in the presence of calcium ions initiates the activation of the extrinsic pathway. This results ultimately in the conversion of fibrinogen to fibrin, with formation of a solid gel. For the IL Coagulation Systems only, the Fibrinogen is quantitated (PT-based method) by relating the absorbance or light-scatter during clotting to a calibrator.

Device Intended Use:

HemosIL RecombiPlasTin 2G is a high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the quantitative determination in human citrated plasma of Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems and Fibrinogen on IL Coagulation Systems only.

The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The performance of HemosIL RecombiPlasTin 2G with a modified phospholipid ratio is not materially different from the FDA cleared device: HemosIL RecombiPlasTin (K043184).

510(k) Summary (Cont.)

Summary of Performance Data:

Precision

Within run and total precision assessed over multiple runs using three levels of control plasma for PT and two levels of control plasma for fibrinogen gave the following results:

ELECTRA	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal	12.2	1.3	1.9
Low Abnormal	21.1	1.2	2.6
High Abnormal	31.3	1.3	3.4

ACL Family	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal	11.7	0.6	1.5
Low Abnormal	21.6	1.0	1.9
High Abnormal	32.9	1.1	2.6

ACL Futura/ACL Advance	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal	12.5	1.1	1.9
Low Abnormal	23.8	1.6	1.9
High Abnormal	36.0	1.8	2.4

ACL TOP	Mean (PT seconds)	CV % (Within run)	CV % (Total)
Normal	11.9	0.8	2.2
Low Abnormal	22.0	0.8	3.1
High Abnormal	34.0	0.9	3.1

ACL Family	Mean (Fibrinogen mg/dL)	CV % (Within run)	CV % (Total)
Normal	319	4.2	5.0
Low Fibrinogen Control	149	5.9	6.9

ACL Futura/ ACL Advance	Mean (Fibrinogen mg/dL)	CV % (Within run)	CV % (Total)
Normal	229	3.0	3.1
Low Fibrinogen Control	157	3.7	4.5

ACL TOP	Mean (Fibrinogen mg/dL)	CV % (Within run)	CV % (Total)
Normal	296	1.4	2.4
Low Fibrinogen Control	135	2.9	3.6

Summary of Performance Data (Cont.):

Method Comparison – In-house

An in-house method comparison study was performed with modified RecombiPlasTin 2G versus the current HemosIL RecombiPlasTin:

System	Assay	Slope	Intercept	r	Reference Method
ELECTRA	PT (Seconds)	0.7637	3.0427	0.9789	HemosIL RTF on ELECTRA
ACL Family		0.7910	2.7860	0.9885	HemosIL RTF on ACL Family
ACL Futura/ ACL Advance		0.8075	2.8899	0.9913	HemosIL RTF on ACL Advance
ACL TOP		0.8010	2.7138	0.9916	HemosIL RTF on ACL TOP
ACL Family	Fibrinogen (mg/dL)	0.9350	6.1043	0.9866	Fibrinogen (PT-Fib based) on ACL Family
ACL Futura/ ACL Advance		0.9711	10.933	0.9783	Fibrinogen (PT-Fib based) on ACL Advance
ACL TOP		1.0129	-3.6298	0.9969	Fibrinogen (PT-Fib based) on ACL TOP

Method Comparison – Field Site

Two field site method comparison studies were performed with modified RecombiPlasTin 2G versus the current HemosIL RecombiPlasTin:

System	Assay	Slope	Intercept	r	Reference Method
ACL TOP	PT (Sec.)	0.8137	4.0035	0.9934	HemosIL RTF on ACL TOP
	PT INR	1.0838	-0.1071	0.9945	
	Fibrinogen (mg/dL)	0.9805	5.3466	0.9946	
System	**Assay**	**Slope**	**Intercept**	**r**	**Reference Method**
ACL 10000	PT (Sec.)	0.7935	2.1733	0.9887	HemosIL RTF on ACL 10000
	PT INR	0.9446	0.0367	0.9881	
	Fibrinogen (mg/dL)	0.9431	7.5763	0.9832	

Expected Values

A normal range study was performed using the modified RecombiPlasTin 2G reagent:

PT	N	Range
• ELECTRA	130	9.8 - 12.2 (seconds)
• ACL Family	130	9.1 - 12.1 (seconds)
• ACL Futura/ACL Advance	130	9.9 - 12.9 (seconds)
• ACL TOP	130	9.4 - 12.5 (seconds)
Fibrinogen	**N**	**Range**
• ACL Family	129	308 - 613 (mg/dL)
• ACL Futura/ACL Advance	129	222 - 340 (mg/dL)
• ACL TOP	129	276 - 471 (mg/dL)

***NOTE:** The product insert advises customers that "These results were obtained using a specific lot of reagent. Due to many variables which may affect clotting times, each laboratory should establish its own normal range."

510(k) Summary (Cont.)
(Summary of Safety and Effectiveness)

Summary of Performance Data (Cont.):

CUBICIN (Daptomycin for injection) Dose-Response Testing

An *in vitro* study indicated no clinically significant CUBICIN (Daptomycin for injection) dose response with the modified HemosIL RecombiPlasTin 2G using the following specifications:

NOTE: The expected peak dosing for CUBICIN (Daptomycin for injection) in circulating blood is 75µg/mL.

- Normal Sample ± 1 second from unspiked sample
- Coumadin Sample ± 10% recovery of the unspiked sample

Data from this testing on representative IL Coagulation Systems are provided below:

ACL 6000 Coagulation Analyzer				
CUBICIN Concentration (µg/mL)	Normal Sample (PT Seconds)	Change in Seconds	Coumadin Sample (PT Seconds)	% Recovery
0	10.5	--	22.5	--
1	10.5	0.0	22.7	101%
10	10.6	0.1	23.0	102%
25	10.5	0.0	23.4	104%
50	10.6	0.1	24.0	107%
100	10.9	0.4	24.8	110%
125	11.0	0.5	24.7	110%

ACL 10000 Coagulation Analyzer				
CUBICIN Concentration (µg/mL)	Normal Sample (PT Seconds)	Change in Seconds	Coumadin Sample (PT Seconds)	% Recovery
0	11.7	--	25.1	--
1	11.7	0.0	25.3	101%
10	11.8	0.1	25.7	102%
25	11.9	0.2	25.9	103%
50	12.0	0.3	26.4	105%
100	12.4	0.7	26.9	107%
125	12.4	0.7	27.5	110%

Summary of Performance Data (Cont.):

CUBICIN (Daptomycin for injection) Dose-Response Testing (Cont.)

ACL Advance Coagulation Analyzer				
CUBICIN Concentration (µg/mL)	Normal Sample (PT Seconds)	Change in Seconds	Coumadin Sample (PT Seconds)	% Recovery
0	12.7	--	26.9	--
1	12.8	0.1	26.8	100%
10	12.6	0.1	27.6	103%
25	12.8	0.1	27.3	101%
50	12.8	0.1	28.4	106%
100	13.2	0.5	29.2	109%
125	13.2	0.5	29.5	110%

ACL TOP Coagulation Analyzer				
CUBICIN Concentration (µg/mL)	Normal Sample (PT Seconds)	Change in Seconds	Coumadin Sample (PT Seconds)	% Recovery
0	12.3	--	27.3	--
1	12.3	0.0	27.4	100%
10	12.3	0.0	27.8	102%
25	12.5	0.2	27.8	102%
50	12.6	0.3	28.4	104%
100	12.8	0.5	29.3	107%
125	12.9	0.6	29.7	109%

ELECTRA 1600C Coagulation Analyzer				
CUBICIN Concentration (µg/mL)	Normal Sample (PT Seconds)	Change in Seconds	Coumadin Sample (PT Seconds)	% Recovery
0	12.2	--	23.1	--
1	12.4	0.2	23.6	102%
10	12.3	0.1	22.0	95%
25	12.6	0.4	24.0	104%
50	12.4	0.2	24.2	105%
100	12.8	0.6	23.4	101%
125	12.7	0.5	24.6	106%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 2007

Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k070005
Trade/Device Name: HemosIL RecombiPlasTin 2G
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS, GIS
Dated: March 22, 2007
Received: March 23, 2007

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

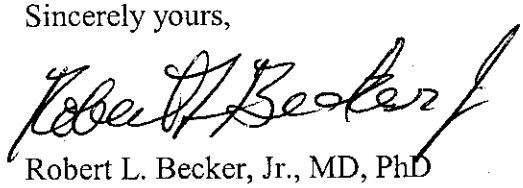
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
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Enclosure

Indications for Use Statement

510(k) Number (if known): K070005

Device Name: HemosIL RecombiPlasTin 2G

Indications for Use:

A high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the quantitative *in vitro* diagnostic determination in human citrated plasma of Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems and Fibrinogen on IL Coagulation Systems only.

The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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